

UNITED STATES OF AMERICA)	
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v.)	NO.: 2:13-CR-56
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ANINDYA KUMAR SEN)	

On June 11, 2014, the defendant was sentenced by the Court to serve a three year term of probation in this case. Several special conditions of probation were imposed by the Court.

- You must establish and implement protocols for your practice and submit those to the probation office for approval to guarantee compliance with the applicable FDA regulations and the Food, Drug and Cosmetic Act. You shall assure that all of the employees of your practice are complying with applicable regulations and ordering FDA approved prescription drugs. You must submit that protocol to the probation office within sixty (60) days.

- You shall submit for inspection by the probation office the records of your practice related to drug purchases and use at least quarterly. If the probation officer needs assistance in determining compliance with the law, the probation officer may in his or her discretion hire a person to do that, and you will bear the costs of that.

- You shall not hire any non-medical personnel for your practice without prior approval of the probation officer and that the hiring of any medical staff is to be done by a medically trained person.

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been raised?”¹ The defendant objected to these conditions on the basis that they are not reasonably related to the offense and, specifically as to the first listed above, that the probation office does not possess the necessary expertise to determine whether Dr. Sen is complying with the applicable FDA regulations and the Food, Drug and Cosmetic Act. Dr. Sen’s objections were orally overruled.

During the sentencing hearing of Dr. Sen, the Court exhaustively examined the 18 U.S.C. § 3553(a) factors as they relate to this case. As the Court discussed, the use of unapproved and misbranded drugs is a serious offense which raises significant concerns about the safety and protection of the public. Special conditions of probation are appropriate if they are reasonably related to the twin goals of probation: Rehabilitation of the defendant, and the protection of the public. *See United States v. Arnold*, 549 Fed. App’x 491 (6th Cir. 2013) (citing *United States v. Doyle*, 711 F.3d 729, 734 (6th Cir. 2013)).

It is undisputed in this case that Dr. Sen used non-FDA approved and misbranded drugs in his practice. As noted in other orders of the Court, FDA approval is required to assure that drugs are safe and effective for their intended use. The use of non-approved and misbranded drugs raises serious safety concerns for the public and requiring compliance with FDA requirements is specifically and directly related to that purpose and to the specific offenses committed by Dr. Sen here.

During the trial and other proceedings in this case, Dr. Sen and his wife, Mrs. Sen, have both adamantly maintained that they did not know they were ordering unapproved drugs and did not know that those unapproved drugs were being administered to patients. Dr. Sen denied ever having anything to do with the ordering of drugs for his oncology practice. At the sentencing

¹ See *United States v. Bostic*, 371 F.3d 865 (6th Cir. 2004); *United States v. Vonner*, 516 F.3d 382, 385-86, 390-91 (6th Cir. 2008).

hearing, Mrs. Sen, in direct contradiction of the clear trial testimony of a number of witnesses at trial, claimed that she did not order the unapproved drugs and never saw those drugs once they were received by the practice. Mrs. Sen attempted to shift the blame for the use of unapproved drugs to the practice's physician assistant and/or the nurses employed there. The requirement that staff be required to become knowledgeable of and comply with applicable regulations is likewise directly related to the criminal conduct in this case.

Mrs. Sen has no medical training whatsoever; yet, during the trial, numerous nurses testified that they were hired by Mrs. Sen and that Mrs. Sen made all hiring and/or firing decisions for the practice. This appears, in the Court's view, to have contributed to the commission of the offense. Thus, requiring Dr. Sen or another medically trained person to be directly involved in the hiring of medical staff and seeking approval from the probation office to hire non-medical personnel is clearly related to the offense conviction. Finally, defense counsel's objection on the basis that the probation office may not have the necessary expertise to determine whether or not the practice is in compliance with applicable laws and regulations is well taken and is the reason for the Court's also providing that if the probation officer needs professional assistance in determining compliance, the probation officer may in his or her discretion hire such a person, and the cost for that will be borne by Dr. Sen.

The objections to the special conditions of probation are DENIED.

So ordered.

ENTER:

s/J. RONNIE GREER
UNITED STATES DISTRICT JUDGE